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CERTIFICATE OF MAILING PURSUANT TO 37 C.F.R. §§ 1.6 and 1.8

I, Joyce D. Brown, hereby certify that this correspondence, pursuant to 37 C.F.R. §§ 1.6 and 1.8, is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Box Non-Fee Amendment, U.S. Patent and Trademark Office, P.O. Box 2327, Arlington, VA 22202, and is being sent via facsimile to 703 308-4556 on:

Date: December 6, 2001By Joyce D. BrownIN THE UNITED STATES PATENT AND
TRADEMARK OFFICE

Applicant(s):	Woodrow C. Monte	Docket No.:	32166.00002
Application No.:	09/747,078	Group Art Unit:	1615
Filing Date:	December 21, 2000	Examiner:	Jiang, S.
TITLE:	ADDING HEAT-SENSITIVE BIOLOGICALLY ACTIVE MATERIAL TO FOOD OR COSMETIC COMPOSITIONS		

RESPONSE PURSUANT TO 37 C.F.R. §1.111

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Commissioner:

ELECTION

In response to the Examiner's Office Action mailed November 6, 2001 requiring an election between Group I (Claims 1-24), Group II (Claims 25-41), Group III (Claims 42-43) and Group IV (Claims 44-46), Group I is hereby elected with traverse.

There are two criteria for a proper requirement for restriction between patentably distinct inventions: (a) the inventions must be independent or distinct as claimed; and (b) there must be a serious burden on the examiner if restriction is required. MPEP 803. "For the purposes of the

initial [restriction] requirement, a serious burden on the examiner may be *prima facie* shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search as defined in MPEP § 808.02." MPEP 803. Examiners must provide reasons and/or examples to support conclusions, to support a restriction requirement. MPEP 803. Applicant respectfully submits the Examiner has not established a proper basis for requiring restriction of Applicant's claims under 35 U.S.C. § 121 and respectfully traverses the requirement for the following reasons.

The Examiner has divided the claims into four groups: Group I (Claims 1-24), Group II (Claims 25-41), Group III (Claims 42-43) and Group IV (Claims 44-46). The Examiner contends that the groups are separate and distinct because each has a different function. The Examiner contends that Group I is distinct because it functions to add a heat-sensitive active material such as an enzyme or antibody to a composition. The Examiner contends that Group II is distinct because it functions to add a lactose-converting active to a lactose-containing composition and further convert at least some of the lactose in the lactose-containing composition to another substance. The Examiner contends that Group III is distinct because it is drawn to a device for imparting a beneficial effect to a composition. The Examiner contends that Group IV is distinct because it is draft to a tablet. The Examiner concludes that the groupings have acquired a separate status in the art because of their recognized divergent subject matter. Applicant respectfully disagrees.

Regarding the Examiner's arguments for Groups I and II, this "invention relates to a method for adding one or more heat sensitive, biologically active materials (such as lactase enzyme) to a composition, such as a food or cosmetic composition, at an elevated temperature that would normally destroy or denature the active material(s)." Applicant's Specification, p. 1, ll. 6-9 (Emphasis added). Lactose-converting enzymes are one specific example of heat sensitive, biologically active material. *Id.*, at p. 2, l. 5 - p. 3, l. 17.

Regarding the Examiner's arguments for Groups I, II, III and IV, "[o]ne aspect of the invention is a method for adding a structure or device including an active to a composition wherein the structure or device temporarily prevents at least some of the active from coming into direct contact with the composition, thus enabling the active to provide a beneficial effect." *Id.*, at p. 5, ll. 17-22 (Emphasis Added). An example of the structure of device is the tablet. *Id.* at p.

6, ll. 2-7. "[B]eneficial effect' means a measurable desired change to a composition due to the presence of an active added to the composition." *Id.* at p. 1, ll. 21-22. Thus, Applicant submits that the groupings made by the Examiner all relate to the same invention. The functional delineations made by the Examiners of Applicant's invention are not supported by Applicant's disclosure.

Further, the groupings made by the Examiner are further unsupported by any division in class or subclass. In fact, the Examiner concedes that all the claims fall into class 424, subclass 464. Thus, for all the foregoing reasons, the Examiner has not established that there is a "serious burden" of examining the alleged inventions of Groups I, II, III, and IV as required under MPEP 803. Applicant respectfully requests the Examiner to reconsider and withdraw the Restriction Requirement. If there are any issues which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

Applicant hereby petitions for any extension of time which may be required to maintain the pendency of this case, and any required fee, except for the Issue Fee, for such extension is to be charged to **Deposit Account No. 19-3878**.

Applicant reserves the right to petition to overrule the restriction requirement and/or to pursue the non-elected claims in a continuing application.

Respectfully submitted,

12/6/01
Date

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